

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Rogers et al.

Application No. 10/533,412

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For: HEAT PASTEURIZED LIQUIDS
CONTAINING GLUCOSAMINE

Examiner: Elli Peselev

Art Unit: 1623

Attorney Reference No. CGL02/0396US03

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DECLARATION BY TODD BANNER PURSUANT TO 37 C.F.R § 1.132

I, Todd Banner, Ph.D., M.B.A., hereby declare as follows:

1. I received a Ph.D. in Organic Chemistry at the University of Memphis (2008). I also received a M.S. in Organic Chemistry from the University of Memphis (2007), an M.B.A. in Marketing from the University of Memphis (2007), and a B.S. in Biochemistry from the University of Missouri, Columbia (2000).

2. I currently am the Chemistry Team Leader in the BioTDC business unit of Cargill, Incorporated, Eddyville, IA. Cargill, Incorporated (Cargill) is the Assignee of Application No. 10/533,412. I have been employed by Cargill since 2008, and was previously employed by Cargill from 2000-2004. While employed in the Acidulants research and development unit of Cargill in 2002-2003, I conducted research on glucosamine stability in aqueous solutions. My research specialties currently include glucosamine stability for applications in food and beverages, and organic and analytical chemistry of food ingredients and bio-based chemicals.

3. It is my understanding that certain claims of the present application are rejected in the Office action dated February 12, 2009, as allegedly being obvious over U.S. Patent No. 6,432,929 to Stone et al. (Stone).

4. I understand that in the Office action dated February 12, 2009, the Examiner alleges it would be obvious to prepare a beverage by first adding glucosamine to the beverage and then subsequently heat pasteurizing the beverage containing glucosamine. I disagree.

5. In my opinion, at the time of the present invention, it was not obvious to conclude that glucosamine could be added to an aqueous solution prior to heat pasteurization without a significant amount of glucosamine degradation occurring as a result of the heat pasteurization process. In fact, at the time, those of us with experience with glucosamine believed that addition of glucosamine prior to heat pasteurization would degrade the glucosamine. Evidence of this belief is provided in the paragraphs below.

6. Stone discusses the limitations of heat pasteurizing glucosamine by stating that the method provided in the patent of adding glucosamine after the pasteurization step "insures that the cartilage supplement is not affected by the preparation and/or bottling process." (Column 8, lines 13-17.) Stone also states that "the total residence time of the cartilage solution at elevated temperatures is minimal, thereby minimizing any heat inactivation of the cartilage supplement." (Column 8, lines 43-46.) Stone explicitly states that the glucosamine containing solution can be pasteurized only if the pasteurization processes "do not include heat processing." (Column 9, lines 1-6.) Thus, even Stone was aware that it was thought to be undesirable to heat pasteurize the glucosamine.

7. The basis for the limitations described by Stone was well known to those of us working in the field of glucosamine. Glucosamine contains both amino and reducing sugar functions in the same molecule. The result is that glucosamine can undergo Maillard-type chemical degradation reactions in aqueous solutions when heated.

8. Experiments were performed at Cargill to validate the belief that glucosamine is unstable in aqueous solution when heated for a period of time at high temperatures. These experiments were performed in August 2008. The results are shown in the attached Appendix A. In a first experiment, glucosamine was combined with a proprietary blend of food and beverage ingredients (carbohydrates, food color, etc.) and was heated at 60 °C, 70 °C, 80 °C, or 90 °C for

15 minutes, and the percent recovery of glucosamine was measured. The upper bar graph shows that glucosamine stability clearly decreased as the temperature increased. In a second experiment, a solution of glucosamine and the food and beverage ingredients was heated at 200 °F, and the percent recovery of glucosamine was determined after 10, 15, 20, 25, and 30 minutes. As shown in the bottom line graph, the percent recovery of glucosamine decreased significantly over time when heated at 200 °F, with 50% degradation after about 25 minutes.

9. At the time of the present invention, I and others in the field of glucosamine chemistry had concluded that glucosamine was unstable in aqueous solutions and would degrade when heated, such as during heat pasteurization. Accordingly, it is my opinion that a person skilled in the art of glucosamine chemistry and applications at the time of the present invention would not have read Stone and concluded that it was obvious to heat-pasteurize beverages containing glucosamine. Instead, I and others in the field concluded that glucosamine should not be added to beverages prior to pasteurization due to likely degradation.

10. All statements made herein and of my own knowledge are true and all statements made on information are believed to be true; and further, these statements were made with the knowledge that willful false statements and like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that any such willful false statements made may jeopardize the validity of the application or any patent issuing thereon.

Date 5/28/09


Todd Banner, Ph.D., MBA